REMARKS/ARGUMENTS

Claims 1, 3-6, 9-15, 17-21, and 24-34 are pending in this application. Claims 1 and 20 have been amended to further state that the average diameter of said particles is from about 20 to about 400 microns, and support for such amendment can be found on page 8, lines 30-31 of the specification. New claims 31-34 find support in original claim 7. Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims.

Provisional Double Patenting Rejection

Claims 1, 4, and 9-12 remained provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatebale over claims 13-15, 19, and 26 of copending application no. 10/697,546 (the '546 Application) in view of Clemente (US patent No. 6,126,967). See Pages 2-4 of the Office Action. The '546 Application is still pending in the U.S. Patent Office and has not issued as a patent. Additionally, Applicant expects that this provisional double patenting rejection will be the only rejection remaining following consideration of this amendment. As set forth in MPEP §804(a):

> ... "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent.

Applicants, therefore, respectfully request withdrawal of this provisional rejection.

Rejections Under 35 USC 103

Claims 1, 3-6, 9-15, 17-21, and 24-30 were rejected under 35 USC 103(a) as being unpatentable over Shah et al. (US 6,126,969) in combination with Singh et al. (US 5,759,579) in view of Sakamoto et al. (US 4828840). See pages 7-11 of Office Action. According to the Office Action:

> "Shah et al. teach a dosage form comprising an extended release portion (abstract). The extended release portion comprises coated core particles where the coating comprises an enteric polymer . . . . Singh et al. teaches a pharmaceutical acceptable liquid suspension system provided for solid finely divided pharmaceutical actives . . . . Singh teaches various examples of liquid suspension systems in columns 4-7 wherein the concentrations of the drug is about 3.2% and the water content is at least 40%. . . . The difference between the invention of the instant application and that of Shah et al. and Singh is that the instant invention claims the use of particles of an NSAID and/or acetaminophen being coated with a controlled release composition comprising one layer of an insoluble film forming polymer and an enteric polymer in a weight ratio of about 80:20 to about 99:1 wherein the pharmaceutical liquid suspension dosage form has a duration of therapeutic effect for at least 12 hours. For this reason, the teaching of Sakamoto et al. is joined. Sakamoto et al. teach a controlled release formulation comprising a coated dosage form wherein the coating comprises a combination of water-insoluble polymers and enteric polymers. . . . It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the cited references to arrive at a pharmaceutical liquid suspension dosage form comprising particles of an NSAID and/or acetaminophen being substantially covered with one layer of a controlled release composition. (emphasis added)"

Applicants respectfully disagree.

As previously argued in the prior amendment, independent claims 1 and 20 recite a pharmaceutical liquid suspension dosage form comprising particles of an NSAID and/or acetaminophen, wherein at least 99% of said particles are covered with one layer of a controlled release composition wherein said controlled release composition is comprises of an insoluble film forming polymer and an enteric polymer, wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1. The benefit of such a coating is that (i) it protects the particles from dissolution in the suspension and (ii) when it enters the intestinal tact, the relatively lesser amount of the enteric polymer dissolves, creating openings in the layer that still comprises the insoluble film forming polymer through which the NSAID and/or acetaminophen can be released. Such a coated particle, and accordingly a suspension containing such a particle, is not taught, nor suggested, by the above references alone or in view of each other.

As discussed above, Singh fails to disclose controlled release coated particles. Further, Shah et al. fails to disclose the coating of particles with an enteric polymer. The Office Action asserts that Sakamoto et al. discloses particles containing enteric polymers. While this may be true, there is no teaching or suggestion in Sakamoto et al. that such a particles would be suitable for use in a suspension. Further, in looking at the examples of Sakamoto et al., the particles

were filled into hard gelatin capsules (see Reference Examples 4-6 of Sakamoto et al.), not suspended within a liquid dosage form. Still further, none of the examples of Sakamoto et al. describe particles containing an NSAID and/or acetaminophen. In fact, Sakamoto et al. does not even disclose that its particles are suitable for acetaminophen or an NSAID. Still further, most particles disclosed in the examples of Sakamoto et al. are quite large (500-1500 microns) and, thus, not typically used in suspensions. As discussed above, Applicants have amended independent claims 1 and 20 to state that "the average diameter of said particles is from about 20 to about 400 microns." Thus, Applicants assert that one of ordinary skill in the art would not look towards Sakamoto et al. in designing a sustained release suspension for an NSAID and/or acetaminophen.

Still further, Applicants have added new claims 28-31 which state that "the pKa of said NSAID is greater than the pH of the liquid suspension pharmaceutical dosage form." Applicants have found that maintaining the pH of the liquid suspension pharmaceutical dosage form lower than the pKa of the active agent inhibits the NSAID from being solubilized in the suspension, which would otherwise compromise the sustained release property of the coated particles. Such an adjustment to the pH of the liquid suspension pharmaceutical dosage form containing the particles recited in the pending claims is also not taught, nor suggested, in the cited references.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP5021/WEM.

Respectfully submitted,

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